



MAR 21 2003

8508 Cross Park Dr.  
Austin, Texas 78754  
512-873-0033  
Fax: 512-873-9090  
[www.int-bio.com](http://www.int-bio.com)

~~510(k) STATEMENT OF SAFETY AND EFFECTIVENESS~~

**510k SUMMARY OF SAFETY AND EFFECTIVENESS  
RADIATION ATTENUATING SURGICAL GLOVE**

Manufacturer: International Biomedical, Inc.  
8508 Cross Park Drive  
Austin, TX 78754  
U.S.A.

Regulatory Affairs Contact: Amy Pieper  
8508 Cross Park Dr.  
Austin, TX 78754

Telephone: (512) 873-0033

Date Summary Prepare: August 27, 2002

Common Name: Powder-Free Radiation Attenuating Surgical Glove

Classification: Surgeon's Glove, 79KGO

Predicate Devices: Radiation Attenuating Surgical Glove by International Biomedical, Inc. (82k1720) and the ESP Radiation Recustion Examination Gloves by Boston Scientific (k891968) and BarrierPlus Synthetic Powder-Free Surgical Gloves y BarrierMed Glove Company (k990710).

Description: The Powder-Free Radiation Attenuating Surgical Gloves are formulated using neoprene, synthetic latex. The gloves are supplied powder-free and sterile.

Intended Use: A powder-free surgeon's glove is intended to be worn on the hands, usually in a surgical setting, to provide a barrier against potentially infectious materials and other contaminants. Additionally, the radiation attenuating surgical glove is intended to

be used during medical procedures where hands are necessarily exposed to radiation in order to offer some degree of protection to the hand from radiation. This includes surgical procedures that require the use of fluoroscopy or radiography.

Substantial Equivalence: Powder Free Radiation Attenuating Surgical gloves are substantially equivalent to the Radiation Attenuating Surgical Gloves in that they have the same intended use, they are both made of synthetic latex, and they are both manufactured in the same way. The Powder Free Radiation Attenuating Surgical gloves are substantially equivalent to the ESP Radiation Recustion Examination Gloves by Boston Scientific in that they have the same intended use and polymers. The Powder Free Radiation Attenuating Surgical gloves are substantially equivalent to the BarrierPlus Synthetic Powder-Free Surgical Gloves in intended use, design and product features, and physical characteristics.

Summary of Test Results:

| <u>Test</u>                     | <u>Result</u>   |
|---------------------------------|---|
| Primary Skin Irritation         | Glove does not display irritation potential.  |
| Dermal Sensitization            | Glove does not display sensitization potential.   |
| Elongation and Tensile Strength | Glove meets or exceeds requirements for synthetic surgical gloves per ASTM D 3577-01a.  |
| Barrier Defects                 | Glove meets or exceeds requirements per ASTM D3577-01a.                                 |
| Powder Level                    | Glove meets powder level requirements for "Powder Free" designation per ASTM D 6124-01. |



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

MAR 21 2003

Ms. Amy Pieper  
Regulatory Affairs  
International Biomedical, Incorporated  
8508 Cross Park Drive  
Austin, Texas 78754

Re: K022873

Trade/Device Name: Radiation Attenuating Neoprene Surgical Gloves,  
Powder Free (Black)  
Regulation Number: 878.4460  
Regulation Name: Surgeon's Glove  
Regulatory Class: I  
Product Code: KGO  
Dated: November 25, 2002  
Received: January 21, 2003

Dear Ms. Pieper:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

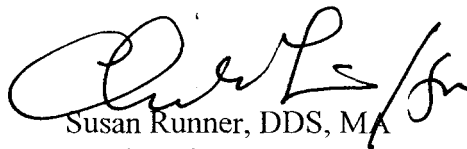
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4618. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "Susan Runner" with a stylized flourish at the end.

Susan Runner, DDS, MA

Interim Director

Division of Anesthesiology, General Hospital,

Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

**510k SUBMISSION FOR THE  
RADIATION ATTENUATING SURGICAL GLOVE (BLACK)**

**INDICATIONS FOR USE**

**Applicant's Name:**

International Biomedical, Inc.

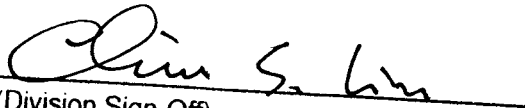
**510(k) Number:** K 022873

**Device Name:**

Neoprene  
Radiation Attenuating Surgical Gloves, Power Free (BLACK)

**Indications for Use:**

A powder-free surgeon's glove is a device made of synthetic latex that may bear a trace amount of glove powder and is intended to be worn on the hands, usually in surgical settings, to provide a barrier against potentially infectious materials and other contaminants. The radiation attenuating surgical glove is intended to be used during medical procedures where hands are necessarily exposed to radiation in order to offer some degree of protection to the hand from radiation. This includes surgical procedures that require the use of fluoroscopy or radiography.

  
(Division Sign-Off)  
Division of Anesthesiology, General Hospital,  
Infection Control, Dental Devices

510(k) Number: K 022873